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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/701,278	08/22/1996	DAVID J. ANDERSON	A-63770-1/RF	5313

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EXAMINER
HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/701,278	Applicant(s) Anderson et al
	Examiner Robert C. Hayes, Ph.D.	Art Unit 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 5, 2003* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 2, and 4-7* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 2, and 4-7* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/5/03 has been entered.

2. Applicant's arguments filed 05/05/03 have been fully considered but they are not deemed to be persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-2 & 4-7 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility, for the reasons made of record in Paper Nos. 26 (mailed 5/3/00), 29 (mailed 1/16/01), 33 (mailed 7/24/01), 36 (mailed 12/17/01) & 38 (mailed 7/23/02), and as follows.

Applicants argue on pages 3-5 of the response *Brooktree Corp v. Advanced Micro Devices, Inc., In re Brana* and *In re Gazave.* Applicants then argue that "the claims of the

present invention are supported by a specific utility, namely that the DRG11 polynucleotides and the proteins expressed thereby can be use to identify, by nuclear staining, a subset of sensory neurons, since DRG11 is expressed in a very specific subset of sensory neurons and not expressed in sympathetic ganglia..."; thereby, "mak[ing] the DRG11 protein a significant marker for identifying certain cell types when studying neuronal development", and refers to page 20 & 32 of the specification. In contrast to Applicants' assertions, page 32 states that

"[t]he expression of DRG11 in E13.5 trigeminal sensory ganglia as well as in trunk DRG appeared *broader* than that of trks A, B or C in nearby sections.... Rather, the extent of DRG11 expression was similar to that of SCG10... or Isl-1, two markers which *label all neurons* in these sensory ganglia. In addition, DRG11 expression was *detected in both small and large DRG neurons* at E17.5; in contrast the larger neurons expressed trksB and C but not A... [emphasis added]."

Thus, DRG11 is not a "specific" marker of a "very specific subset of sensory neurons", as argued by Applicants, but a "general" marker "similar to that of SCG10... or Isl-1", which therefore refers to a general class of compounds. Thus, no "specific" utility exists, as previously made of record.

Second, because "basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved" does "not define 'substantial utilities'" (see the Utility Guidelines), no "substantial" utility exists. As previously made of record, further experimentation is still necessary at the time of filing the instant invention to attribute a "real world" utility to the claimed polynucleotides (i.e., as it relates to establishing a "substantial" utility), which Applicants appear to acknowledge on pages 4 & 5 of the response, as

it relates to such statements as "will prove as an important marker for further understanding in the area of Pain perception" or "can also be exploited to gain insight into the phenotypes and behavior of specific cell types". Moreover, what a 2001 reference discloses 5 years after the filing date of the instant application does not overcome the rejection of record, because the court in *Vas-Cath Inc. v. Mahurkar,* 19 USPQ2d 1111, 1117, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, *as of the filing date sought*, he or she was in possession *of the claimed invention* [emphasis added]". Therefore, because no assayable function for the DRG11 of the instant invention is known in the art nor adequately described within the instant specification, and because no related disease state, etc. is known in the art nor specifically described within the specification, an invitation to discover such alternatively supports the rejection of record that no "substantial" utility exists at the time of filing Applicants' invention.

In conclusion, because no known nor described function existed for the DRG11 protein of SEQ ID NO:2, or for polynucleotides that encoded such (e.g., SEQ ID NO:1), at the time of filing the instant invention, no "specific" nor "substantial" utility exists, which further remains consistent with that decided by the courts in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966) previously made of record, in contrast to Applicants' assertions.

5. Claims 1-2 & 4-7 stand also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility

or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, for the reasons made of record in Paper Nos: 26, 29, 36 & 38.

6. Claims 1 & 5-7 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper No. 26, 29, 33, 36 & 38, and as follows.

Applicants argue on pages 6-7 of the response that "[c]laim 1 is no longer defined by hybridization to SEQ ID NO:1" , that "[t]he description in the specification is clearly sufficient to demonstrate that applicants had the subject matter of claim 1 in his possession as of the filing of the present application", and cites *Purdue Pharma L.P. v. Faulding Inc.* In contrast to Applicants' assertions, the issue remains that one of ordinary skill in the art cannot reasonably visualize what generic nucleic acid sequences are specifically encompassed by the current claims (i.e., as it relates to the undescribed "at least 70%" identity language claimed). Nor could one reasonably visualize what constitutes generic sequences encompassed by these claims based solely on the written description of the *single* cDNA sequence of SEQ ID NO:1, which has no known and assayable function, for the reasons previously made of record; consistent with that held by the courts in *Fiers v. Revel, Fiddes v. Baird, Univ. California v. Eli Lilly and Co.*

previously made of record. Thus, in contrast to Applicants' arguments, Applicants are clearly not in possession of the claimed genus at the time of filing Applicants' invention.

Applicant is again directed toward the Revised Interim Written Description and Utility Guidelines, Federal Register, Vol.64, No.244, pages 71427-71440, Tuesday December 21, 1999. See especially, Examples 11 & 17.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert C. Hayes, Ph.D.
June 17, 2003
pat. exp.